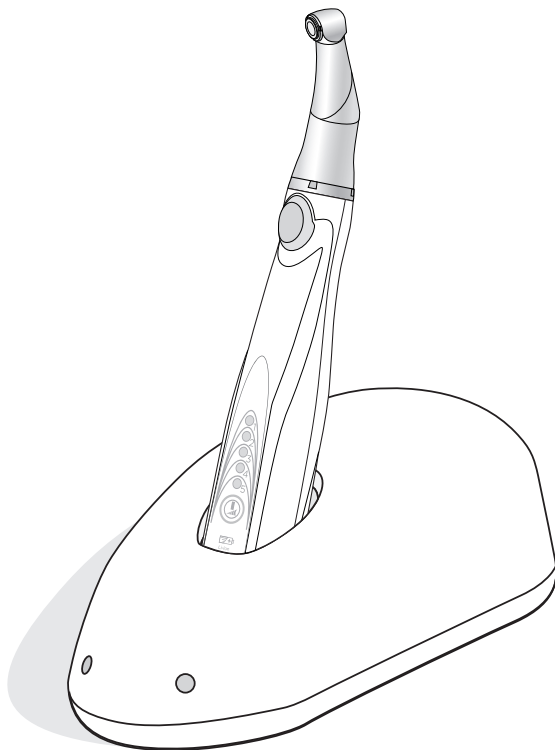


Instructions for use of S5 Endo Motor



Sendline Symbols



WARNING!
(Risk of injury)



ATTENTION!
(to prevent damage occurring)



General explanations,
without risk to
persons or objects



Thermo washer disinfectable



Sterilizable
up to the stated temperature










Sendline Service

Only for USA

Caution: Federal law restricts this device to sale by or on the order of a dentist, physician or any other practitioner licensed by the law of the state in which he or she practices to use or order the use of the device.

Sendoline Symbols

Symbols on rechargeable battery / charging station / contra-angle head / drive handpiece

	Consult Instructions for use		Do not dispose of in general waste	REF	Catalogue number
				SN	Serial number
	Class II equipment (electric insulating)		Data Matrix Code, for product identification e.g. in hygienic maintenance process	V	Supply voltage
				AC	Alternating current
	Date of manufacture		Classification mark, that this product is in compliance with the American and Canadian safety requirements	W	Electric power input of the unit
				A	Supply current
				Hz	Frequency of the alternating current
	Not suitable for intracardiac application – Type BF appliance			rpm	Revolutions per minute
				mAh	Milliampere hours
				Ncm	Newton centimetres

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1. Introduction



For your safety and the safety of your patients

These instructions explain to you how to handle your Sendoline product. However, we must also warn against possible hazardous situations. Your safety, the safety of your team, and of course, the safety of your patients is of paramount importance to us.



It is therefore essential to read the safety notes on pages 8 to 10.

Intended use

The Sendoline S5 Endo Motor is a modular electrical system comprising a drive handpiece, a rechargeable battery, a contra-angle head and a charging station for mechanical preparation of the root canal. The application area extends to endodontic procedures using a special root canal instrument which is intended by the manufacturer for use in the mechanical and rotary preparation of the root canal.

Misuse can damage the S5 Endo Motor and involves risk and danger to the user and third parties.


User qualifications

In the development and design of the S5 Endo Motor, we have assumed the target group of users to be dentists.

Skilled application


This medical product is intended only for informed use in the medical dental field, according to its purpose of use in compliance with the valid health and safety at work regulations, the valid accident prevention regulations as well as in compliance with these Instructions for Use. The S5 Endo Motor should be maintained according to the manufacturer's recommendations and in line with infection control procedures for the safety and well-being of patients. Improper use, e.g. poor hygienic maintenance, or non-compliance with our Instructions or the use of accessories and spare parts which are not approved by Sendoline, invalidates all claims under warranty and any other claims.

Introduction


 **Production according to EU directive**
0413 This medical product has been designed and manufactured according to EU Directive 93/42/EEC and is valid for the

> S5 Endo Motor (charging station, drive handpiece, contra-angle head and rechargeable battery Li-Ion 3.7 V)

in the condition as delivered by us. This declaration is not valid for unintended external or internal attachments and similar.

 **Responsibility of the manufacturer**
Sendoline AB in Täby, Sweden can only accept responsibility for the safety, reliability and performance of the S5 Endo Motor when there is compliance with the following directions:

- > The S5 Endo Motor must be used in accordance with these Instructions for Use.
- > The S5 Endo Motor contains no parts which are repairable by the user. Assembly, modifications or repairs must be carried out only by an authorized service organisation (see page 33).
- > The electrical installation at the premises must comply with the international regulations of IEC 60364-7-710 ("Electrical installations of buildings – Part 7-710: Requirements for special installations or locations – Medical locations") or with the regulations applicable in your country.

 **HF Communication Devices**
During operation, please do not use any portable or mobile high-frequency communication devices (such as mobile telephones). These can have a negative effect on electrical medical devices.

2. Equipment supplied

After unpacking the following parts should be present:

REF 1100010

- ☐ drive handpiece REF 1100001
- ☐ contra-angle head REF 1100002
- ☐ charging station REF 1100003
- ☐ rechargeable battery Li-Ion 3.7 V REF 1100004

- ☐ mains cable REF 05464400 (Europe)

alternative specification:

- ☐ mains cable REF 05456100 (USA, CAN, J) / REF 05457700 (UK, IRL) / REF 05467600 (AUS, NZ)

3. Safety notes



It is essential to comply with the following instructions

- > Always ensure the correct operating conditions.
- > Perform a test run prior to each use.
- > Only use REF 1100002 Sendoline contra-angle head.
- > Only insert the contra-angle head when the drive handpiece is stationary.
- > Check the contra-angle head for damage and loose parts prior to use (e.g. press button).
- > Never touch the press button of the contra-angle head during use or while slowing down. This can cause loosening of the root canal instrument or the press button to become hot.
- > Avoid contact between the instrument head and soft tissue (danger of burning due to the press-button heating up).
- > Use only perfect root canal instruments and follow the manufacturer's instructions.
- > Only insert the root canal instrument when the contra-angle head is stationary.
- > Never touch root canal instruments while running or slowing down.
- > The drive handpiece should only be placed in the holder as it may heat up. Do not place it on the patient's body!
- > Sendoline recommends the use of rubber dam.
- > Store drive handpiece and charging station for 24 hours at room temperature before starting operation.



Hygienic maintenance prior to initial use

The items are in a clean condition when delivered.

- > Sterilize and lubricate the contra-angle head,
- > disinfect the drive handpiece and charging station prior to initial use (see page 20 – 25).



Inappropriate use

Improper use, in addition to incorrect assembly, installation, modification or repairs of the S5 Endo Motor or non-compliance with our instructions invalidates all claims under warranty and any other claims!

Safety notes



It is essential to comply with the following instructions when using the rechargeable battery.

- > The rechargeable battery Li-Ion 3.7 V is not sterilizable.
- > Only use REF 1100004 Sendoline rechargeable batteries. Using a different model of battery can cause a fire or explosion.
- > Only use the Sendoline rechargeable battery REF 1100004 in connection with the Sendoline drive handpiece REF 1100001 and the battery charging station REF 1100003.
- > The rechargeable battery used in the device can cause a risk of fire or acid burns if it is not used properly (e.g. charging in a charging station other than the one provided).
- > The battery may not be dismantled, heated to above 100 °C (212 °F), or burned.
- > Defective or disused rechargeable batteries must be immediately disposed of in the correct manner.
- > Keep the rechargeable battery out of the reach of children.

The S5 Endo Motor (charging station / drive handpiece)

The unit is classed as "conventional equipment" (closed equipment without protection against the ingress of water).

System failure

A total system failure of the S5 Endo Motor does not constitute a critical fault.

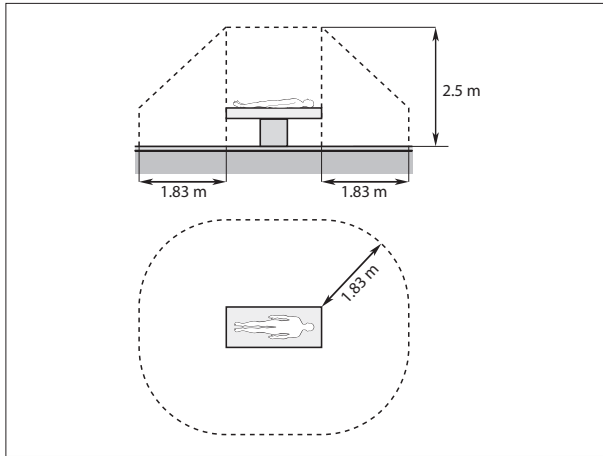


The charging station has been adjusted to fit the Sendoline drive handpiece. The use of other charging stations / drive handpieces could lead to irregularities or destruction of the electronic system / rechargeable battery.



According to IEC 60601-1 / UL 60601-1, the S5 Endo Motor must not be used in potentially explosive atmospheres or in potentially explosive mixtures of anesthetics with air, oxygen or nitrous oxide, or at locations where concentrations of such gases could occur (closed rooms).

Safety notes

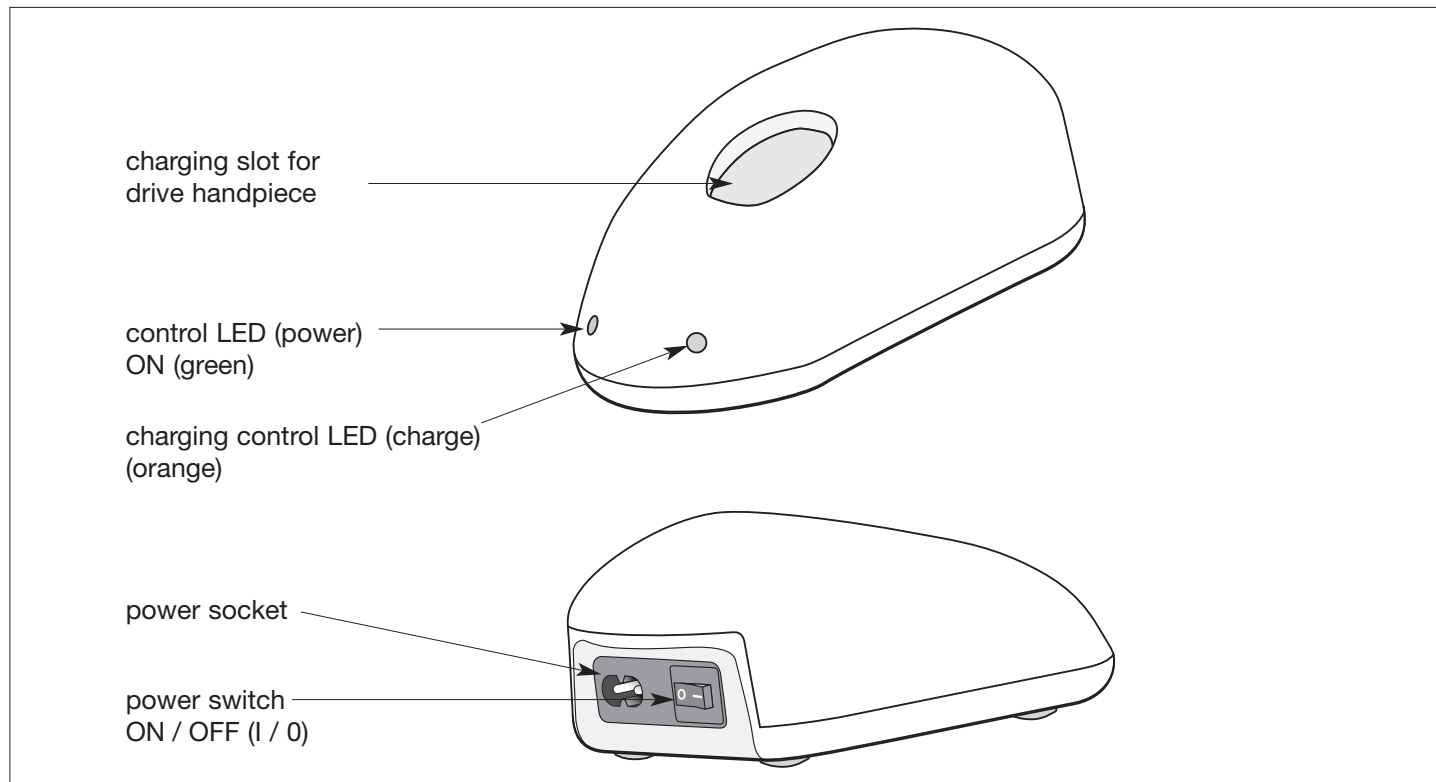


The “patient zone” (see diagram) represents an area of 2.50 m above and 1.83 m around the patient.

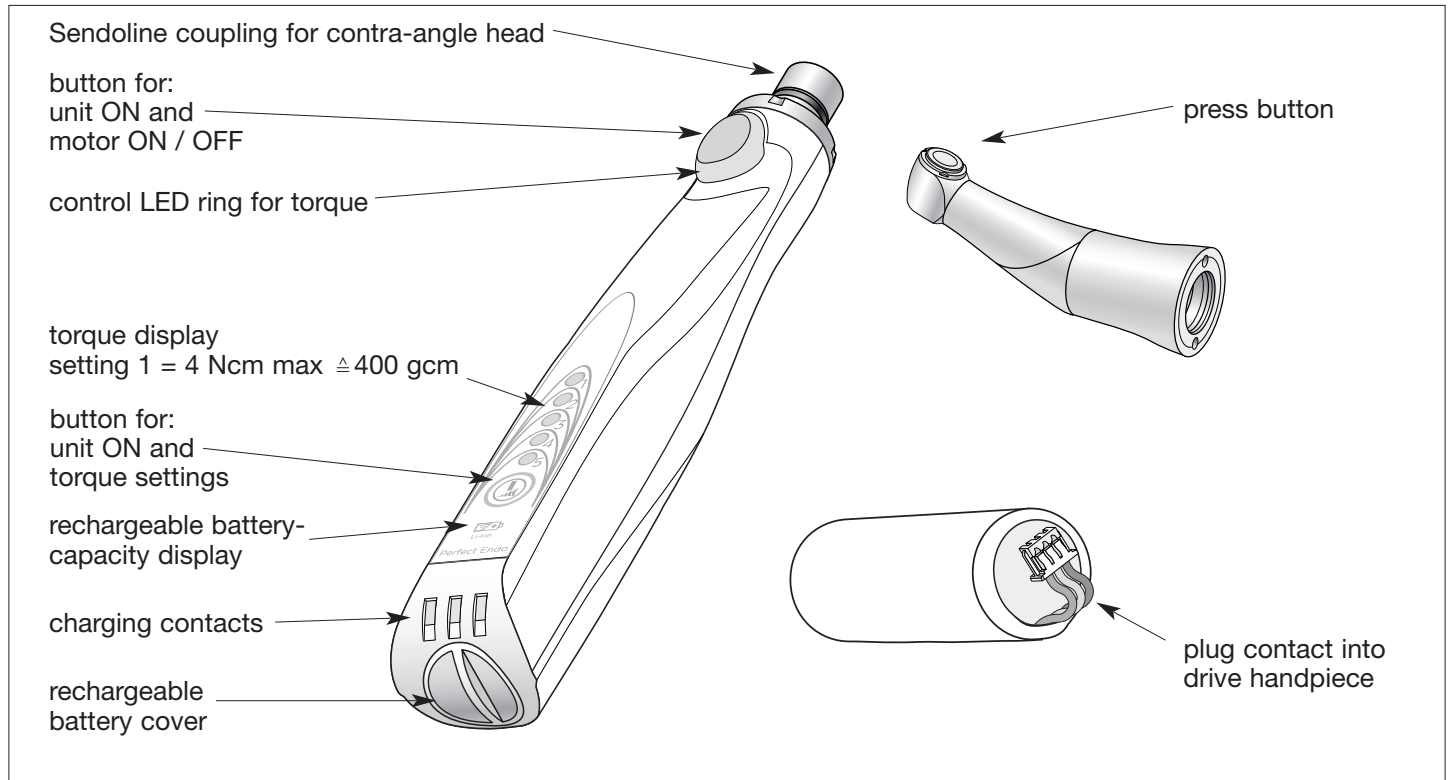


Do not use the charging station in the patient zone.

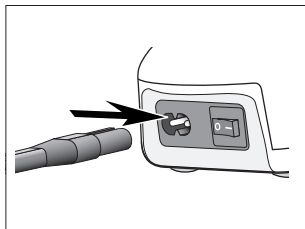
4. Description – Charging station



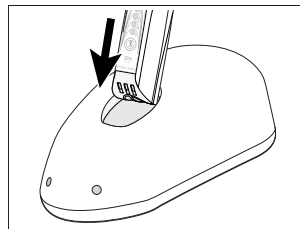
5. Description – Drive handpiece / Rechargeable battery / Contra-angle head



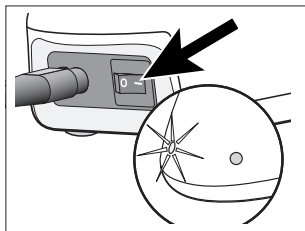
6. Starting operation – Charging station



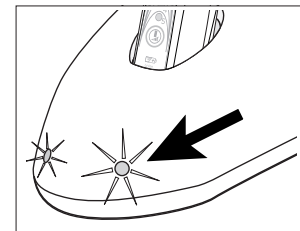
❶ Connect the mains cable.



❷ Place the drive handpiece in the charging station.
Note the positioning.
All the drive handpiece LEDs light up briefly.



❸ Turn on power switch.
The green control-LED (power) comes on.



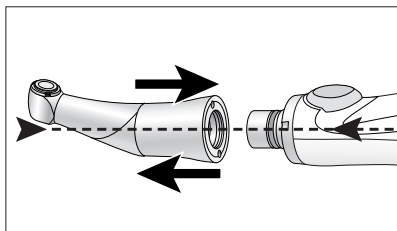
❹ Rechargeable battery is charging.
Orange charging control LED (charge) comes on.

- The drive handpiece can remain in the switched on charging station until it is next needed.
- Fully charge the battery prior to initial use. This process takes approx. 100 minutes.
- The rechargeable battery is fully charged when the orange LED goes out.

7. Starting operation – Assembly / removal of the contra-angle head



Only change the contra-angle head when the drive handpiece is stationary.

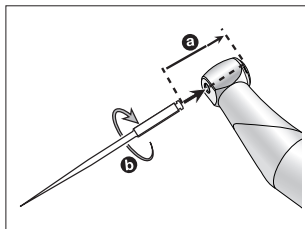


- ➊ Push on the contra-angle head by applying slight axial pressure (position selectable).
- ➋ Remove the contra-angle head by applying slight axial tension.

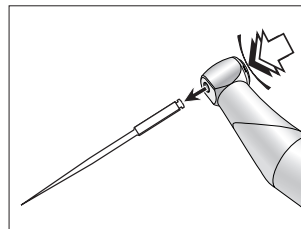
8. Changing the root canal instrument



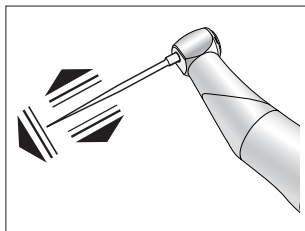
Only change the root canal instrument when the drive handpiece is at a complete standstill.



- ❶ Push in the root canal instrument as far as the locating lug (a) and turn until it engages (b).



- ❸ Remove the root canal instrument by pushing the press button.

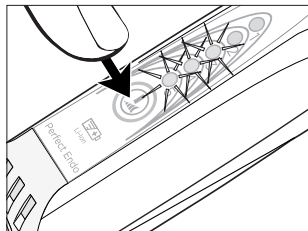


- ❷ Check secure location by applying slight axial tension.

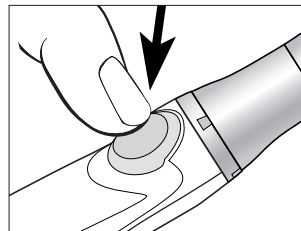
Test run

- > Insert root canal instrument.
- > Start the drive handpiece.
- > If you observe problems (e.g. vibrations, unusual noise or excessive heating) **stop operation of the drive handpiece immediately** and contact an authorized service organization (see page 33).

9. Operating – Adjust torque



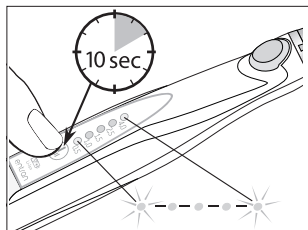
- 1 Adjust the torque.
Preset torque is characterized by the illuminated LEDs.



- 2 Start or stop the drive handpiece with the button motor ON / OFF.
If you press the motor ON / OFF button for more than approx. 1 second, the drive handpiece will stop auto-matically when you let go.

- > For information about the torques to be set, see the attached torque overview or sendoline.com.
- > The torque can only be set when the drive handpiece is stationary.
- > The last torque setting is saved.
- > The drive handpiece switches off after it has been idle for 4 minutes.
- > When the battery capacity display begins to flash, a minimum of one more application is possible. After this appears, Sendoline recommends that the battery should be recharged immediately as otherwise it cannot be ensured that the torque values will be achieved.

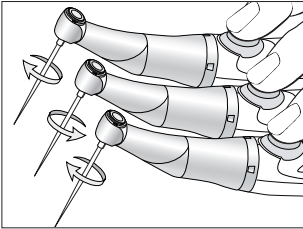
Adjusting torque sequence (from low to high torque):



- 1 Press the torque settings button for approx. 10 seconds.
The middle 3 LEDs flash after 5 seconds.
- 2 The change in torque sequence is saved when the 2 outer LEDs flash.
To change the factory-set torque sequence again (from high to low torque), repeat this process.

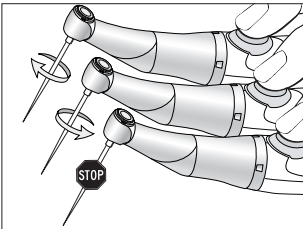
10. Operating – Auto Forward and Auto Reverse mode

The factory setting is Auto Forward mode:



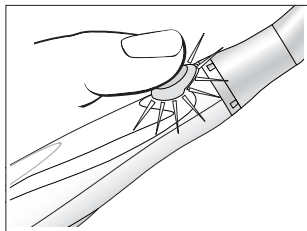
If the preset torque is reached, the drive handpiece continues running in an anti-clockwise direction so that the root canal instrument becomes free and then it runs in a clockwise direction.

Auto Reverse mode:



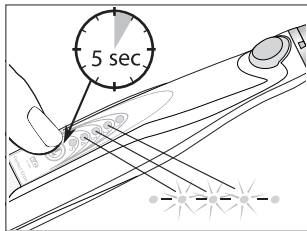
If the preset torque is reached, the drive handpiece continues running in an anti-clockwise direction so that the root canal instrument becomes free and then it stops.

Operating – Auto Forward and Auto Reverse mode



If more than 75 % of the preset torque is reached, the control LED ring for torque lights up.

Conversion to Auto Reverse mode:



- ❶ Press the torque settings button for approx. 5 seconds.
- ❷ When the middle 3 LEDs flash the mode change is saved.



The last torque set is retained.





Repeat the procedure in order to change back to the Auto Forward mode.

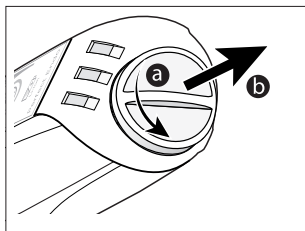


Restore factory settings: Press and hold the torque settings button for approx. 15 seconds.
The LEDs flash in a particular sequence (see page 26) and afterwards the factory setting has been restored.

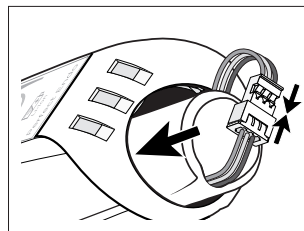
11. Exchanging the rechargeable battery


 Replace the battery if power fails relatively quickly after a full charge.

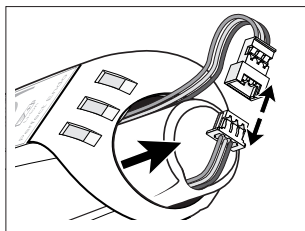
 In order to avoid damaging the device, one should avoid opening the battery cover unnecessarily.



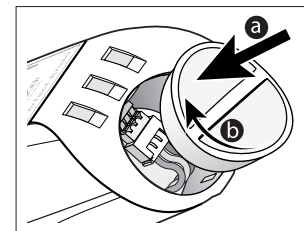
1 Take the cover off.




3 Insert the new rechargeable battery. Connect the plug contacts.
 Note the positioning.



2 Disconnect the plug contacts. Take the rechargeable battery out.



4 Close the cover.
 Note the positioning.

12. Hygienic maintenance



Follow your country-specific directives, standards and guidelines for cleaning, disinfection and sterilization.



- > Wear protective clothing.
- > Remove the root canal instrument.
- > Remove the contra-angle head from the drive handpiece.

- > Clean and disinfect the contra-angle head **immediately after every treatment** to rinse out any liquids that may have entered (e.g. blood, saliva, etc.) and prevent seizing up of the internal parts.
- > Clean and disinfect the drive handpiece **immediately after every treatment**.

- > Sterilize the contra-angle head following manual or mechanical cleaning, disinfection and lubrication.
- > The charging station and drive handpiece are not approved for mechanical cleaning (thermo washer disinfection) and sterilisation.

Hygienic maintenance

Charging station and drive handpiece



- > The mains cable of the charging station must not be connected.
- > Do not submerge the drive handpiece and the charging station or clean them under running water.

Pre-disinfection

- > If heavily soiled: Clean first with disinfectant cloths.

Manual cleaning and disinfection



The surface of the charging station and drive handpiece may be wiped clean.


- > For disinfection with surface disinfectants, wiping disinfection is recommended.
- > Use only surface disinfectants which do not contain chlorine and which are certified by officially recognized institutes.
For USA: Use EPA registered surface disinfectants.
- > Note the manufacturer's specifications for the use of the surface disinfectants.

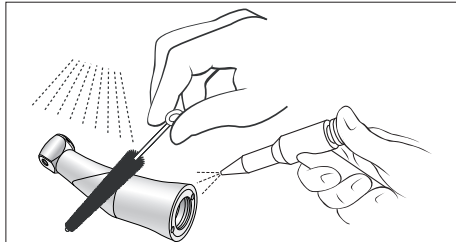
Hygienic maintenance

contra-angle head

Pre-disinfection

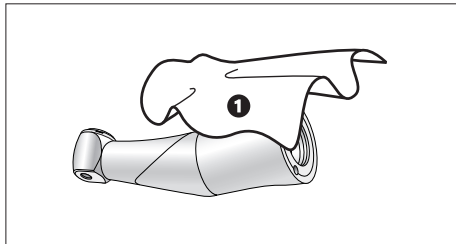
> If heavily soiled: Clean first with disinfectant cloths.

 Only use disinfectants that have no protein-fixing effects.



Manual cleaning (internal and external)

- ❶ Rinse under demineralized water ($< 38^{\circ}\text{C}$) with the aid of a brush (brushing under running water is not recommended in U.K.)
- ❷ Then remove any liquid residues (absorbent cloth, blow dry with compressed air).



Manual disinfection

- > Disinfection with surface disinfectants, ❶ wiping disinfection is recommended.
- > Use only surface disinfectants which do not contain chlorine and which are certified by officially recognized institutes. For USA: Use EPA registered surface disinfectants.
- > Note the manufacturer's specifications for the use of the surface disinfectants.



After manual cleaning, disinfection and lubrication you must carry out a final sterilization (wrapped) in a class B or S steam sterilizer (according to EN 13060).

Hygienic maintenance

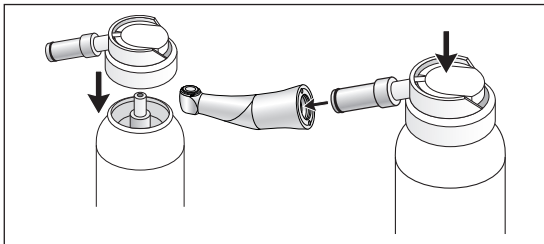
Mechanical cleaning and disinfection



Sendoline recommends processing in a thermo washer disinfectant.
Follow the manufacturer's recommendations for devices and cleaning agents.



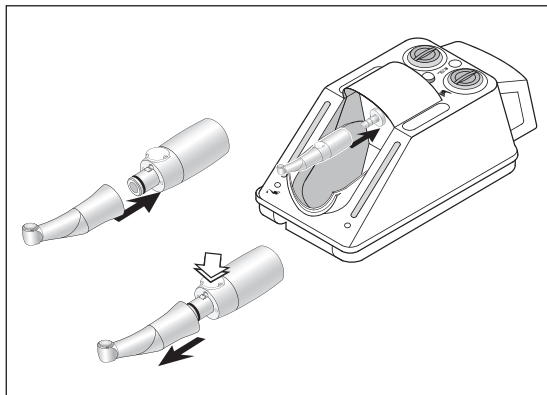
Lubricate contra-angle head immediately after thermo washer disinfection.



Daily oil service with W&H Service Oil F1, MD-400

> Follow the instructions for use of the oil spray can.

Hygienic maintenance



Daily oil service service with W&H Assistina

> See instructions for use of Assistina.

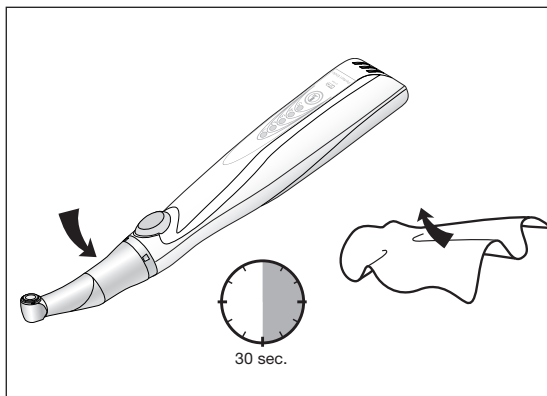
- ❶ Push the universal adaptor onto the contra-angle head.
- ❷ Assemble / remove the appropriate adaptor onto the maintenance attachment of the Assistina.
- ❸ Push the button and remove the universal adaptor from the contra-angle head.

Recommended lubrication cycles (W&H Service Oil F1 und Assistina)

- > Essential after internal cleaning
 - > Before each sterilization
- or
- > After 30 minutes of use or
 - > At least once daily

Test run following oil service

- ❶ Push the contra-angle head onto the drive handpiece.
 - ❷ Place the contra-angle head with head downwards.
 - ❸ Run the drive handpiece for 30 seconds to remove excess oil.
- > Repeat the entire hygienic maintenance process if dirt emerges.
- ❹ Wipe the contra-angle head and the drive handpiece with gauze or a soft cloth.




Hygienic maintenance

Sterilization and storage

 Sendoline recommends sterilization according to EN 13060, class B

- > Note the instructions of the unit manufacturer.
- > Clean, disinfect and lubricate before sterilizing.
- > Wrap the contra-angle head in sterile goods packing according to EN 868-5.
- > Make sure that you only remove dry sterile goods.
- > Store sterile goods dust-free and dry.

Approved sterilization procedures

 Follow your country-specific directives, standards and guidelines.

- > Steam sterilization class B with sterilizers in accordance with EN 13060.
Sterilization holding time a minimum of 3 minutes at 134 °C (273.2 °F)
- or
- > Steam sterilization class S with sterilizers in accordance with EN 13060.
The manufacturer must give their express approval for the sterilization of contra-angles.
Sterilization holding time a minimum of 3 minutes at 134 °C (273.2 °F)

13. Description of failure / Remedy

Drive handpiece:

Description	Remedy
The drive handpiece cannot be activated.	The rechargeable battery is empty. Charge or change it.
Internal error - all 5 LEDs on the torque display are flashing.	Restore factory settings. (press and hold the torque settings button for approx. 15 seconds. After the first 5 seconds the middle 3 LEDs flash, after a further 5 seconds the 2 outer LEDs flash and after a further 5 seconds only the middle LED continues to flash, this indicates that the factory settings have been restored).
System failure	Disconnect / Connect the rechargeable battery.
The rechargeable battery heats up excessively.	Change the rechargeable battery.

Charging station:

Description	Remedy
Charging control LED (charge) flashes orange.	Remove and reinsert the drive handpiece.
No LED illuminates.	Check that the mains cable is plugged in and that the power switch is set to ON (I).



If one of the error messages described above cannot be rectified by remedy, the equipment must be checked by a service and repair organization authorized by Sendoline (see Page 33).

14. Servicing



Regular checking of the S5 Endo Motor

Regular testing of function and safety is necessary, and should be carried out at least once every three years, unless shorter intervals are prescribed by law. The inspection must be undertaken by a qualified organization and needs to include the following procedures:

Charging station

- > visual inspection for outside damage
- > measurement of housing leakage current
- > visual inspection of internal components and electronic boards on suspicion of safety interference,
e. g. mechanical damage of the enclosure or indicators for overheated or burned (electronic) components

Drive handpiece

- > visual inspection for outside damage
- > visual inspection of internal components and electronic boards on suspicion of safety interference,
e. g. mechanical damage of the enclosure or indicators for overheated or burned (electronic) components

We recommend that this inspection is only carried out by an authorized service organization (see page 33).

Servicing

Repairs

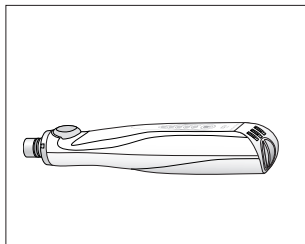
If a defect occurs, always return the complete S5 Endo Motor, due to the fact that with malfunctions, an inspection of all components is necessary!

Returns

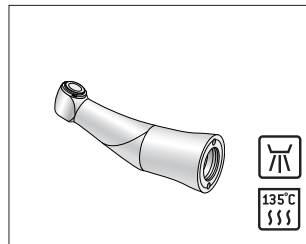
- > Refer all questions to your authorized service organization (see page 33).
- > Always return equipment in the original packaging!

15. Sendoline Accessories

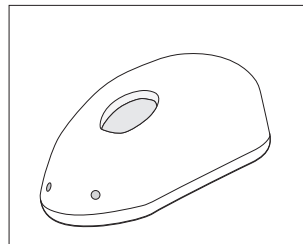
Use only original Sendoline accessories / spare parts
or accessories approved by Sendoline



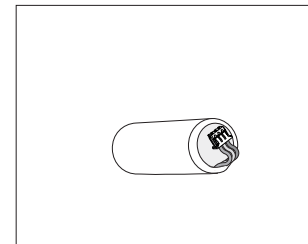
1100001
Drive handpiece



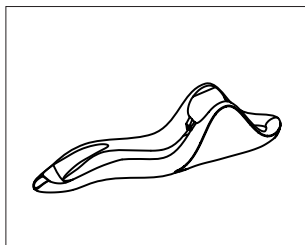
1100002
Contra-angle head



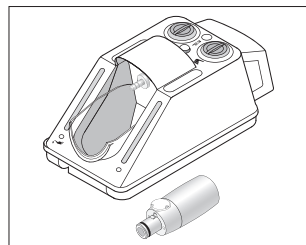
1100003
Charging station



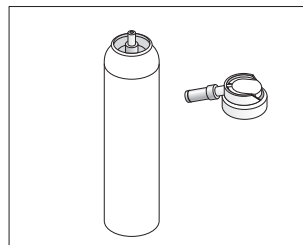
1100004
Rechargeable battery
Li-Ion 3.7 V



1100006
Handpiece holder



301
W&H Assistina
1100005
Universal adaptor for
maintenance units



10940021
W&H Service Oil F1,
MD-400
02038200
Spray cap with nozzle
for contra-angle
handpieces

16. Technical data

Drive handpiece EB-3SH

rechargeable battery type:

Li-Ion

mains voltage:

3.7 V

rated capacity:

680 mAh

rotational speed on root canal instrument:

300 rpm

setting 1 max. 4.0 Ncm

setting 2 max. 3.0 Ncm

setting 3 max. 2.3 Ncm

setting 4 max. 1.2 Ncm

setting 5 max. 0.5 Ncm

dimensions (WxDxH):

140 x 28 x 26 mm

weight:

85 g

Charging station

mains voltage:

100 – 240 V

allowable voltage fluctuation:

+/- 10 %

frequency:

50 – 60 Hz

rated current:

0.08 – 0.12 A

power:

5 W

dimensions (WxDxH):

95 x 159 x 65 mm

weight:

345 g

Technical data

Contra-angle head EB-16S

transmission ratio:	16:1
coupling typ:	Sendoline coupling
recommended root canal instrumente*:	files for rotating root canal preparation for min. 300 rpm
Instrument shaft diameter (type 1) in accordance with EN ISO 1797-1:1995:	Ø 2.35 mm*
min. chuck length:	engaging
weight:	35 g

- * In choosing the correct operating conditions, the user must ensure that there is no risk to the user, the patient or third parties. Always follow the instructions of the manufacturer of the root canal instruments (e.g. in terms of speed, torque, described application).

Physical characteristics

Temperature in storage:	-40 °C (-40 °F) to +70 °C (+158 °F)
Air humidity in storage:	8 % to 80 % (relative), non-condensing at +40 °C (+104 °F)
Temperature in operation:	+10 °C (+50 °F) to +40 °C (+104 °F)
Air humidity in operation:	15 % to 80 % (relative), non-condensing at +40 °C (+104 °F)

Technical data

Recycling

Sendoline considers that it has a special duty towards the environment. The S5 Endo Motor along with its packaging has been designed to be as environmentally friendly as possible.

Disposal of the S5 Endo Motor (charging station / drive handpiece / rechargeable battery / contra-angle head)

Follow your country-specific laws, directives, standards and guidelines for the disposal of used electrical devices.

Disposal of the packaging material

All packaging materials have been selected according to environmental compatibility and disposal aspects and can be recycled. Please send old packaging materials to the relevant collection and reprocessing system. In this way, you will contribute to the recycling of raw materials and the avoidance of waste.

Sendoline Contacts



Sendoline AB, Box 7037 Tillverkarvägen 6 SE-187 11 Täby Sweden

Phone: +46 (0)8 445 88 30, Fax: +46 (0)8 445 88 33, E-mail: info@sendoline.com

Letter of indemnity

This Sendoline product has been manufactured with great care by highly qualified specialists. A wide variety of tests and controls guarantee faultless operation. Please note that claims under warranty can only be validated when all the directions in the Instructions for Use have been followed.

As manufacturer, Sendoline is liable for material or manufacturing defects within a warranty period of 12 months from the date of purchase for the drive handpiece, contra-angle head, charging station and the rechargeable battery Li-Ion 3.7 V.

We accept no responsibility for damage caused by incorrect handling or by repairs carried out by third parties not authorized to do so by Sendoline.

Claims under warranty - accompanied by proof of purchase - must be sent to the vendor or to an authorized Sendoline service point. The provision of service under warranty extends neither the warranty period nor any other guarantee period.

12 Months Warranty

Manufacturer

Sendoline AB
Box 7037 Tillverkarvägen 6 SE-187 11 Täby Sweden

t +46 (0)8 445 88 30, f +46 (0) 8 445 88 33
e info@sendoline.com sendoline.com

ISO 13485,
93/42/EEC – Annex II

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